cytiva

Biosafe S.A.

DECLARATION OF CONFORMITY

Following the provisions of the medical devices directive 93/42/EEC, Annex VII.

We:

Manufacturer

Biosafe S.A.
Route du Petit-Eysins 1
1262 Eysins, Switzerland

EU Authorized Representative

Qarad EC-REP BV
Pas 257
2440 Geel, Belgium

Declare under our sole responsibility that the device:

DISPOSABLE CELL SEPARATION KITS FOR SEPAX™ SYSTEM

A collection of sterile devices that is a component of a blood centrifugation system intended to be used during the centrifugation of blood, relative components or cellular products (e.g., umbilical cord blood, bone marrow), to automatically isolate constituent components (e.g., cells, plasma). The kit is not donor or patient connected and is placed in the centrifuge of the processing unit. It includes a centrifugation chamber into which blood is introduced and sedimented into its components during centrifugation, a stopcock manifold and tubing intended to direct and control the sequential movement of each component, and collection containers. This is a single-use device.

Ref:

Medical Device Name: Sepax™ Cell Separation Kit	
Medical Device Reference	**Catalog Designation**
CS-430.1	10017
CS-470.0	10034
CS-470.1	10005
CS-490.1	10001
CS-530.1	10015
CS-530.4	10024
CS-530.4b	10036
CS-540.4	10025
CS-540.4b	10037
CS-570.1m	10045
CS-570.3m	10046
CS-570.4	10030
CS-570.4mb	10039
CS-600.1	10006
CS-900.2	10008

GMDN Code: 45669

Classification rule (93/42/EC Annex IX) 18 Class IIb

To which this declaration relates, is in conformity with the requirements of the medical devices directive 93/42/EEC that apply to it.

This conformity is based on the following elements:

- For the directive 93/42/EEC (MDD)
  - Technical Documentation/DHF Ref./ réf: Technical File 02 (Disposable Cell Separation Kit), of the product to which this declaration relates.
  - ISO 13485 Certificate: Approval of Quality Assurance System delivered by TÜV SÜD PRODUCT SERVICE GMBH on 06-07-2018/ Certificate N Q5 1804 45171 022
  - Harmonized standards applied on the product to which this declaration relates, see below or Addendum. (Available upon request)

SIGNATURE:

Date of issue:	06-AUG-2021
Place of issue:	Eysins
Name:	Alison Campbell
Function:	Total Quality Leader - PRRC
Signature:	A Campbell

ADDENDUM TO THE DECLARATION OF CONFORMITY 29466924

DISPOSABLE CELL SEPARATION KITS – Accessories and Components

Medical Accessories	Catalog Designation
Sampling line AK 100 (Class Is)	10010
Sampling line AK-101 (Class Is)	10028
DMSO extension line FA-100.1 (Class IIa)	10022
Double Spike Accessory FA-200.1 (Class IIa)	10043

Biosafe S.A. has verified the mutual compatibility of the accessories in combination with Disposable Cell Separation Kit and included relevant information to users with Disposable Cell Separation Kit instructions for use. This activity was subject to appropriate methods of internal control and inspection

Standard
EN ISO 14971 :2019 Medical devices – application of risk management to medical devices
EN ISO 15223-1:2016

Medical devices – symbols to be used with medical device labels, labelling and information to be supplied – part 1: general requirements medical devices – symbols to be used with medical device labels, labelling and information to be supplied – part 1: general requirements
EN 1041:2008 Information supplied by the manufacturer of medical devices
ISO 11135 :2014 Sterilization of health-care products -- Ethylene oxide -- Requirements for the development, validation and routine control of a sterilization process for medical devices.
EN ISO 11737-1 :2006/AC:2009 Sterilization of medical devices -- Microbiological methods -- part 1: Determination of a population of microorganisms on products
EN ISO 11607-1 :2009 Packaging for terminally sterilized medical devices -- part 1: requirements for materials, sterile barrier systems and packaging systems
EN 556-1:2001/AC :2006 Sterilization of medical devices – Requirements for medical devices to be designated 'sterile' - Part 1: Requirements for terminally sterilized medical devices
EN ISO 11607-2 :2006 Packaging for terminally sterilized medical devices - part 2: validation requirements for forming, sealing and assembly processes
EN 20594-1 :1993/A1 :1997 Conical fittings with 6 % luer taper for syringes, needles and certain other medical equipment
ISO 14644-1 :2015 Cleanrooms and associated controlled environments - part 1: Classification of air cleanliness by particle concentration
EN-ISO 10993-1 :2009/AC:2010 Biological evaluation of medical devices - part 1: evaluation and testing
EN-ISO 10993-4 :2009 Biological evaluation of medical devices - part 4: selection of tests for interactions with blood
EN ISO 10993-5 :2009 Biological evaluation of medical devices - part 5: tests for in vitro cytotoxicity
EN ISO 10993-7 :2008/AC: 2009 Biological evaluation of medical devices - part 7: ethylene oxide sterilization residuals
ISO 10993-10 :2010 Biological evaluation of medical devices - part 10: tests for irritation and skin sensitization
EN ISO 10993-11 :2009 Biological evaluation of medical devices - part 11: tests for systemic toxicity
EN-ISO 10993-12 :2012 Biological evaluation of medical devices - part 12: sample preparation and reference materials
EN ISO 10993-18: 2009 Biological evaluation of medical devices - part 18: chemical characterization of materials

End of Document